UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,658	05/18/2005	Amanda Proudfoot	ARS-104	9141

23557 7590 05/14/2007

SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
PO BOX 142950
GAINESVILLE, FL 32614-2950

EXAMINER	
MERTZ, PREMA MARIA	
ART UNIT	**PAPER NUMBER**
1646	

MAIL DATE	DELIVERY MODE
05/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,658	PROUDFOOT ET AL.	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *35-56* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I (claims 22-26 and 31) in the reply filed on 4/30/07 is acknowledged.

Claims 22-34 have been canceled in the amendment filed 4/30/07. New claims 35-56 (4/30/07) are pending and under consideration by the Examiner.

A restriction on new claims 35-56 is set forth below.

2. This application is a 371 of PCT/EP03/50097. For applications filed under 371, PCT rules for lack of unity apply.

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains inventions or groups of inventions, which are not so linked as to form a single inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Groups 1-5. Claims 35-48, 53, drawn to a human MCP-1 antagonist, a nucleic acid encoding a human MCP-1 antagonist, an expression vector, a host cell and a process of preparing the MCP antagonist, wherein the antagonist is selected from a mutant of MCP-1 with mutations:

(a) at amino acids 18 and 19;

(b) at amino acids 18, 19 and 58;

(c) at amino acids 18, 19 and 66;

(d) at amino acids 18, 19, 58 and 66; and

(e) at amino acids 18, 19 and one or more of the following: 24, 44, 49, 75.

Groups 6-10. Claim 54, drawn to a method of reducing leukocyte migration and activation *in vitro* by contacting leukocytes with a human MCP-1 antagonist selected from a mutant of MCP-1 with mutations:

(a) at amino acids 18 and 19;

(b) at amino acids 18, 19 and 58;

(c) at amino acids 18, 19 and 66;

(d) at amino acids 18, 19, 58 and 66; and

(e) at amino acids 18, 19 and one or more of the following: 24, 44, 49, 75.

Groups 11-15. Claims 55-56, drawn to a method of treating a vascular disorder by administering a human MCP-1 antagonist selected from a mutant of MCP-1 with mutations:

(a) at amino acids 18 and 19;

(b) at amino acids 18, 19 and 58;

(c) at amino acids 18, 19 and 66;

(d) at amino acids 18, 19, 58 and 66; and

(e) at amino acids 18, 19 and one or more of the following: 24, 44, 49, 75.

Groups 16-20. Claims 55-56, drawn to a method of treating cancer by administering a human MCP-1 antagonist selected from a mutant of MCP-1 with mutations:

(a) at amino acids 18 and 19;

(b) at amino acids 18, 19 and 58;

(c) at amino acids 18, 19 and 66;

(d) at amino acids 18, 19, 58 and 66; and

(e) at amino acids 18, 19 and one or more of the following: 24, 44, 49, 75.

Groups 21-25. Claims 55-56, drawn to a method of treating inflammatory diseases by administering a human MCP-1 antagonist selected from a mutant of MCP-1 with mutations:

(a) at amino acids 18 and 19;

(b) at amino acids 18, 19 and 58;

(c) at amino acids 18, 19 and 66;

(d) at amino acids 18, 19, 58 and 66; and

(e) at amino acids 18, 19 and one or more of the following: 24, 44, 49, 75.

Groups 26-30. Claims 55-56, drawn to a method of treating autoimmune diseases by administering a human MCP-1 antagonist selected from a mutant of MCP-1 with mutations:

(a) at amino acids 18 and 19;

(b) at amino acids 18, 19 and 58;

(c) at amino acids 18, 19 and 66;

(d) at amino acids 18, 19, 58 and 66; and

(e) at amino acids 18, 19 and one or more of the following: 24, 44, 49, 75.

Groups 31-35. Claims 55-56, drawn to a method of treating infections by administering a human MCP-1 antagonist selected from a mutant of MCP-1 with mutations:

(a) at amino acids 18 and 19;

(b) at amino acids 18, 19 and 58;

(c) at amino acids 18, 19 and 66;

(d) at amino acids 18, 19, 58 and 66; and

(e) at amino acids 18, 19 and one or more of the following: 24, 44, 49, 75.

NOTE: Independent claim 35 encompasses thousands of MCP-1 peptide sequences that are not related in structure, and therefore the claim is considered to comprise an improper Markush group. This claim is not a proper linking claim because it, in fact, comprises multitudes of sequences.

Applicants must choose a single MCP-1 peptide for examination. This is not a species election, but an election of a single invention.

The inventions listed as Groups I-35 do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2 they lack the same or corresponding special technical feature for the following reasons:

Inventions 1-5 and 6-35 are independent and distinct, each from the other, because the methods in inventions 6-35 are practiced with materially different products which are structurally and chemically different, the novelty of the inventions lying in the products being administered

and not the processes. The only feature in common in the instant inventions is "a method of reducing leukocyte migration", which does not constitute the special technical feature lacking from the prior art because this method can be practiced with a composition other than the instant products such as with an antibody to eotaxin or an antibody to the colony stimulating factors. Distinctness is further shown because each of these products in each method can be made and used without any one or more of the other products. The products in the different Groups are physically, chemically and biologically distinct from each other, and if patentable would support separate patents. Furthermore, separate search terms would be required for searching the literature, eg. a search of the literature for an association of the MCP-1 mutant (with mutations at 18, 19 and 58) and cancer would not necessarily reveal art for an association of the MCP-1 mutant (with mutations at 18, 19, 58 and 66) and autoimmune disease. Furthermore, a search of the literature with the MCP-1 mutant (with mutations at 18, 19 and 66) and vascular disease would not necessarily reveal art for an association of the MCP-1 mutant (with mutations at 18, 19, 58, and 66) and vascular disease.

The methods of Groups 6-35 are patentably distinct from each other because each method uses different patient populations, different starting materials and has different goals and the search of all methods in one patent application would result in an undue search burden.

4. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Rejoinder under In re Ochiai and In re Brouwer

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.

See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz

Prema Mertz Ph.D., J.D.
Primary Examiner
Art Unit 1646
May 2, 2007